

U.S. PATENT AND TRADEMARK OFFICE  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND  
INTERFERENCES

JAN 12 2004

*In re the Application of Bach et al.*

Application No.: 08/986,568

Filed: December 5, 1997

Docket No.: 040388/0110

For: **METHOD FOR TREATING ESTABLISHED SPONTANEOUS AUTO-IMMUNE DISEASES IN MAMMALS**

REPLY TO EXAMINER'S ANSWER

Appeal from Group 1644

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## SUMMARY OF THE ARGUMENT

The examiner's comments necessitate a finding that appellants possessed the claimed invention. In addition, the examiner improperly dismisses the working example as insufficient and erroneously demands human testing. Finally, the examiner's obviousness arguments are grounded on erroneous factual assertions.

### II. ARGUMENT

#### A. *The examiner's comments necessitate a finding that appellants possessed the claimed invention*

In the Appeal Brief, appellants noted that, “[t]hroughout the specification and prosecution history, the phrase ‘anti-CD3 active compound’ is used to denote non-mitogenic, anti-CD3 antibodies or fragments thereof.”<sup>1</sup> The Examiner’s Answer conceded this construction<sup>2</sup> and acknowledged that the specification provided numerous examples of representative compounds.<sup>3</sup> Thus, the examiner’s present comments substantiate the conclusion that one of skill in the art would have recognized that appellants possessed the claimed invention at the time of filing. For this reason alone, the appealed rejection should be overruled.

#### B. *The examiner improperly dismisses appellants’ working example and erroneously demands human testing*

In his Answer, the examiner confessed to lacking the technical expertise to question the adequacy of the nonobese diabetic (NOD) mouse as a model for human insulin-dependent diabetes mellitus (IDDM).<sup>4</sup> In addition, the examiner admitted that those possessing the requisite skill “generally acknowledge that NOD mice are a model for human diabetes.”<sup>5</sup>

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<sup>1</sup> Appeal Brief filed June 18, 2003, pg. 5, ¶ 6.

<sup>2</sup> Examiner’s Answer, dated November 12, 2003, paragraph spanning pg. 8-9.

<sup>3</sup> *Id.* at pg. 4, ¶ 2.

<sup>4</sup> *Id.* at pg. 9, ¶ 2.

<sup>5</sup> *Id.* at pg. 9, ¶ 2.

Thus, it is apparent that the examiner has committed a legal error by dismissing out of hand the status of that model as a “working example.”<sup>6</sup>

Apparently finding the current law too restrictive, the examiner also has enunciated a new “enablement” standard, requiring human testing for claims directed to the treatment of humans.<sup>7</sup> According to the examiner, “appellant must jump through a higher hoop to establish enablement than did Brana.”

As appellants’ Brief emphasized, it is well-established that “Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.”<sup>8</sup> Like the examiner whose decision the Federal Circuit addressed in *In re Brana*, the examiner in this case “confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption.”<sup>9</sup>

In light of the examiner’s numerous legal errors, the appealed rejection under Section 112 should be overruled.

*C. The examiner’s obviousness arguments are grounded on erroneous factual assertions*

In supporting his obviousness rejection, the examiner made a number of factual assertions. According to the examiner, Chatenoud treated NOD mice with overt diabetes with F(ab')<sub>2</sub> fragments of an anti-CD3 antibody.<sup>10</sup> The examiner further alleged that such treatment induced a durable effect until the mice were sacrificed at 4 months.<sup>11</sup> The examiner also urged that claims 1-2, 4, 6, 9-13 and 17-18 encompass the “whole anti-CD3 antibody” used by Chatenoud.

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<sup>6</sup> See e.g. MPEP §2164.02(g) (Feb. 2003), pg. 2100-181.

<sup>7</sup> Examiner’s Answer, dated November 12, 2003, pg. 11-12.

<sup>8</sup> *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994).

<sup>9</sup> *In re Brana*, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995).

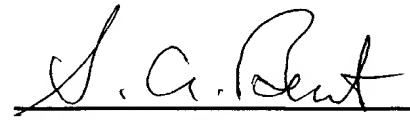
<sup>10</sup> Examiner’s Answer, dated November 12, 2003, pg. 6, ¶ 3, pg. 12, ¶ 2.

<sup>11</sup> *Id.* at pg. 13, ¶ 2.

Each of these assertions is erroneous as a matter of fact, however. As evident from the record, appellants have addressed each of these items on numerous occasions during the six years of prosecution. Accordingly, the appealed rejection under §103 should be overruled.

Respectfully submitted,

12 January 2004  
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